K133058

FEB 2 5 2014

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: 09/10/2013

2. Sponsor Identification

Wenzhou Wuzhou Import & Export Co., Ltd.
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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Name: Insulin Pen Needle
Proposed Device Common Name: Insulin Pen Needle

Regulatory Information:
Classification Name: Needle, Hypodermic, Single Lumen;
Classification: 2;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570;
Review Panel: General Hospital;

Intended Use Statement:
The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

5. Predicate Device Identification

510(k) Number: K120690
Product Name: insulin pen needle
Manufacturer: Tiger Medical Products Ltd.

6. Device Description

The proposed device, Insulin Pen Needle, is a single-use device, which is designed for use with a pen injector for the subcutaneous injection of insulin. It consists of needle tube, hub, tube sheath, hub sheath and sealed paper. The hub can be connected screwed onto the insulin pen.

The Insulin Pen Needle is offered in various gauge sized and length.

They are provided sterilized with Sterility Assurance Level (SAL) of 10^{-6}.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7864 Third edition 1993-05-15, Sterile hypodermic needles for single use.
ISO 9626 First edition 1991-09-01, AMENDMENT 1 2001-06-01 Stainless steel needle tubing for the

manufacture of medical devices.

ISO 11608-2 Second edition 2012-04-01, Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles

ISO 10993-7:2008(R) 2012, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

ISO 11737-2:2009, Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

USP 35-NF30:2012, <85> Bacterial Endotoxins Test.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	FMI	Same
Regulation Number	21 CFR 880.5570	Same
Class	Class II	Same
Intended Use	The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
Configuration	Needle Tube, Hub, Tube Sheath, Hub Sheath and Sealed Paper	Similar
Operation mode	Manual	Same
Needle Gauge	29G/30G/31G/32G	Same
Performance specification	Comply with ISO 7864, ISO 9626, and ISO 11608-2	Same
Material	Tube: 304 Stainless Steel	Same
	Hub: Polypropylene	Same
Sterilization	SAL:10^{-6}	Same
	EO Sterilized	Same
Shelf Life	5 years	Same
Single Use	Yes	Same
Labeling and Labels	Meet FDA requirements	Same

The proposed device, Insulin Pen Needle, is determined to be Substantially Equivalent (SE) to the predicate device, insulin pen needle (K120690), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Wenzhou Wuzhou Import & Export Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K133058
Trade/Device Name: Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 18, 2013
Received: September 27, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133058

Device Name
Insulin Pen Needle

Indications for Use *(Describe)*
The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA
Digitally signed by
Richard C. Chapman
Date: 2014.02.25
12:54:03 -05'00'